K122067

## Section 5.0

## 510(k) Summary

otometrics

SEP 27 2012

### 510(k) Information

| New Device | |
|---|---|
| **Submission Type:** | Traditional |
| **Reason for Submission:** | New Device |
| **Device/Trade Name:** | Type 1077 Accuscreen / Type 1077 Madsen Accuscreen |
| **Common Name:** | Evoked Response Auditory Stimulator |
| **Classification Name:** | Stimulator, Auditory, Evoked Response |
| **FDA CFR Section:** | FDA 21CFR 882.1900 |
| **Classification Panel:** | Neurology |
| **Device Class:** | Class II |
| **Device Product Code:** | GWJ |

| Predicate Device | |
|---|---|
| **Product Name:** | Echo-Screen T, TA, TD, TDA, TC |
| **510(k) Number:** | K013977 |
| **Classification Name:** | Stimulator, Auditory, Evoked Response |
| **FDA CFR Section:** | FDA 21CFR 882.1900 |
| **Device Product Code:** | GWJ |
| **Manufacturer Name:** | Fischer-Zoth Audiologic Systems |

| | |
|---|---|
| **Submitter/Owner:** | GN Otometrics A/S<br>Hoerskaetten 9<br>DK-2630 Taastrup<br>Denmark |
| **Establishment Registration No.:** | 9612197 |
| **Contact:** | Tom Riniker<br>Director RA/QA<br>triniker@gnotometrics.com<br>(612) 865-7862 |
| **Date of Preparation:** | October 10, 2011 |



GN Otometrics A/S | Dybendalsvænget 2, DK-2630 Taastrup, Denmark | Phone + 45 45 75 55 55, Fax + 45 45 75 55 59 | www.otometrics.com, info@gnotometrics.dk | Co. Reg. No. 25384687

# Section 5.0

## 510(k) Summary

otometrics

**Description of the Device**

GN Otometrics Type 1077 AccuScreen is a handheld examination system based on Otoacoustic Emissions (OAE) and/or Auditory Brainstem Response (ABR). Identical techniques are used – among others – on Fischer-Zoth model, Echo-Screen. The Type 1077 AccuScreen is designed to be easy to use, and employs automated OAE and/or ABR tests. The measurement flow is menu-guided and evaluation is based upon signal statistics. The Type 1077 AccuScreen is designed for trained personnel in a medical or home environment to examine hearing in infants from 34 weeks (gestational age) up to 6 months of age that are well enough to be ready for discharge from the hospital.

The Type 1077 AccuScreen OAE system consists of the AccuScreen handheld device, a Docking Station with mains adapter, OAE probe with disposable probe- and ear-tips, and AccuLink software for installation on a PC. When ABR is included an optional ear coupler cable and disposable ear couplers can be included in the system, as well.

The AccuScreen handheld device comes in two hardware versions; one for OAE screening only and one for both OAE and ABR screening. Both versions are based on a common hardware platform (printed circuit board), but with different configurations.

The measurement application is controlled from a self-contained firmware (software) module installed in the handheld device. The firmware module can be configured to allow different OAE measurement types (DPOAE and/or TEOAE) by a license key stored in the device.

For automated OAE measurements, the handheld device uses an OAE probe, designed and manufactured by PATH Medical GmbH. The OAE probe has been granted marketing clearance by the FDA following the submission of a 510(k) (K100661).The OAE probe is fitted with an ear-tip (constructed of biocompatible material) and inserted in the ear canal of the patient. The AccuScreen device plays stimulus sounds in the ear canal via small speakers in the OAE probe. The AccuScreen device measures the patient's response to the stimulus sounds via a microphone in the probe. The measured response is processed by the AccuScreen device using statistics to help determine whether or not a hearing loss may be present.

When the OAE measurement is a DPOAE measurement, the stimulus signal is composed of two pure tone signals, each presented by a speaker in the OAE probe. When the OAE measurement is a TEOAE measurement, the stimulus signal is a series of broadband clicks presented by one speaker in the OAE probe.



GN Otometrics A/S | Dybendalsvænget 2, DK-2630 Taastrup, Denmark | Phone +45 45 75 55 55, Fax +45 45 75 55 59 | www.otometrics.com, info@gnotometrics.dk | Co. Reg. No. 25384687


For automated ABR measurements, the device uses the OAE probe, or an ABR ear coupler cable for providing the acoustical stimulus for the patient. When the ABR ear coupler cable is used, its speakers are inserted in the ABR Ear Couplers, which are then placed over the patient's ear with a biocompatible adhesive gel on the ear coupler rim. The stimulus signal is a series of broadband clicks and the AccuScreen device measures the patient's response as an electrical signal from three electrodes placed on the head of the patient. The measured response is processed by the AccuScreen device using statistics to help determine whether or not a hearing loss may be present.

The 1077 Docking Station serves as a means of providing power to charge the rechargeable battery in the AccuScreen handheld device. The Docking Station also provides an interface to an optional label printer or to a PC. The label printer is used for printing test results from the AccuScreen handheld device. The PC is used for transferring patient demographical data to the AccuScreen handheld device and for collecting measurement results from the AccuScreen handheld device by using the AccuLink PC software.

**Intended Use**

AccuScreen is a portable instrument used to screen infants for hearing loss. The instrument uses the Distortion Product Otoacoustic Emissions (DPOAE), Transient Evoked Otoacoustic Emissions (TEOAE) and Auditory Brainstem Response (ABR) technologies. The instrument is intended for screening infants from 34 weeks (gestational age) up to 6 months of age that are well enough to be ready for discharge from the hospital. Infants should be asleep or in a quiet state at the time of screening. AccuScreen is intended for use by audiologists, ENTs and other health care professionals.

**Comparison to Predicate Device**

The system most similar to the Type 1077 AccuScreen in terms of system components, features and measurement principals is the Echo-Screen (Models T, D, TD, TA, DA, TDA) from Fischer-Zoth Audiologic Systems. The Echo-Screen device has been granted marketing clearance by FDA following the submission of a 510(k).

The following table identifies the existing models of the Echo-Screen device and the corresponding models planned for the 1077 Accuscreen. With the exception of the 1077 Accuscreen ABR model for ABR screening only, all other model combinations between the two devices are the same.



GN Otometrics A/S | Dybendalsvænget 2, DK-2630 Taastrup, Denmark | Phone +45 45 75 55 55, Fax +45 45 75 55 59 | www.otometrics.com, info@gnotometrics.dk | Co. Reg. No. 25384687

otometrics

| Echo-Screen Model Name | Echo-Screen Description | Echo-Screen Model No. | Accuscreen Model Name | Accuscreen Description | Accuscreen Model No. |
|---|---|---|---|---|---|
| Echo-Screen T | Echo-Screen TEOAE | 010109–T | Accuscreen TE | Accuscreen TEOAE | 8-04-13900 |
| | Echo-Screen DPOAE | 010109–D | Accuscreen DP | Accuscreen DPOAE | 8-04-13901 |
| Echo-Screen TD | Echo-Screen TEOAE & DPOAE | 010109–TD | Accuscreen TE/DP | Accuscreen TEOAE & DPOAE | 8-04-13902 |
| Echo-Screen TA | Echo-Screen TEOAE & AABR | 010109–TA | Accuscreen ABR/TE | Accuscreen ABR & TEOAE | 8-04-13904 |
| | Echo-Screen DPOAE & AABR | 010109–DA | Accuscreen ABR/DP | Accuscreen ABR & DPOAE | 8-04-13905 |
| Echo-Screen TDA | Echo-Screen TEOAE, DPOAE, & AABR | 010109–TDA | Accuscreen ABR/TE/DP | Accuscreen ABR, TEOAE, & DPOAE | 8-04-13906 |
| | | | Accuscreen ABR | Accuscreen ABR | 8-04-13903 |

The design and working principals of Type 1077 AccuScreen are very similar to the Echo-Screen with the technological improvements added to the design. This similarity is due largely to the fact that the same engineers at Fischer-Zoth Audiologic Systems that designed the Echo-Screen also provided significant input to the design of the 1077 Accuscreen.

Both systems use a battery driven handheld and portable device with attached OAE probe- and ABR electrode cables.

From a measurement perspective, the two devices utilize the same measurement methods (DPOAE, TEOAE and ABR) and use very similar probes and electrodes. The signal processing and detection methods within the devices are also very similar, and both devices give a Pass/Refer result as an automated screening result.

The primary difference between the two devices is in the mechanical design, display technology and graphical user interface. Here the Echo-Screen uses a larger standard off-the-shelf box for housing, a small and low resolution monochrome display and the user interface is via a 17-key foil keyboard, while the Type 1077 AccuScreen uses a



GN Otometrics A/S | Dybendalsvænget 2, DK-2630 Taastrup, Denmark | Phone + 45 45 75 55 55, Fax + 45 45 75 55 59 | www.otometrics.com, info@gnotometrics.dk | Co. Reg. No. 25384687

specially designed plastic cabinet, a larger, higher resolution color display and the user interface is via a touch sensitive screen.

**Substantial Equivalence Performance Data**

Substantial equivalence to the Echo-Screen is based not only on a side-by-side design comparison, but also on the compliance of both devices to the standards listed below:

| | |
|---|---|
| 1. IEC 60601-1 | Medical Electrical Equipment. Part 1: General requirements for safety |
| 2. IEC 60601-1-2 | Medical Electrical Equipment. Part 1: General requirements for safety. 1. Collateral standard: Electromagnetic compatibility – Requirements and tests |
| 3. IEC 60601-1-4 | Medical Electrical Equipment. Part 1: General requirements for safety. 4. Collateral standard: Programmable electrical medical systems (Design process) |
| 4. IEC 62304 | Medical device software life cycle process |
| 5. IEC 62366 | Medical devices – Application of usability engineering to medical devices |
| 6. ISO 10993-5 | Biological Evaluation of Medical Devices: Tests for Cytotoxicity |
| 7. ISO 10993-10 | Biological Evaluation of Medical Devices: Tests for Irritation and delayed-type hypersensitivity |
| 8. ISO 10993-1 | Biological Evaluation of Medical Devices: Evaluation and Testing |
| 9. ISO 10993-12 | Biological Evaluation of Medical Devices: Sample Preparation and Reference Materials |

The equivalent results from both the Type 1077 Accuscreen and the Echo-Screen obtained when each device was tested or evaluated to determine compliance with the aforementioned standards clearly demonstrates the substantial equivalence between these two devices.

Based on the results of testing to the applicable requirements of the aforementioned standards and achieving compliance to them, we hereby conclude that the Type 1077 Accuscreen device is substantially equivalent to the identified predicate device.



GN Otometrics A/S | Dybendalsvænget 2, DK-2630 Taastrup, Denmark | Phone +45 45 75 55 55, Fax +45 45 75 55 59 | www.otometrics.com, info@gnotometrics.dk | Co. Reg. No. 25384687

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 27 2012

GN Otometrics
c/o Ms. Paula Wilkerson, RAC, CRA
Program Manager
Intertek Testing Services NA, Inc.
2307 East Aurora Road, Unit B7
Twinsburg, OH 44087

Re: K122067
Trade/Device Name: Type 1077 Accuscreen
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: August 6, 2012
Received: August 7, 2012

Dear Ms. Wilkerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

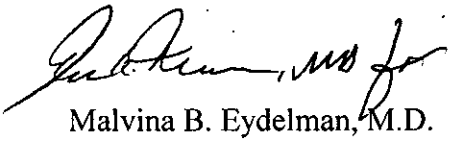
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122067

# Section 4.0

## Indications for Use

510(k) Number (if known): _____

Device Name: Type 1077 AccuScreen

Indications for Use:

**Type 1077 AccuScreen**

AccuScreen is a portable instrument used to screen infants for hearing loss. The instrument uses the Distortion Product Otoacoustic Emissions (DPOAE), Transient Evoked Otoacoustic Emissions (TEOAE) and Auditory Brainstem Response (ABR) technologies. The instrument is intended for screening infants from 34 weeks (gestational age) up to 6 months of age that are well enough to be ready for discharge from the hospital. Infants should be asleep or in a quiet state at the time of screening. AccuScreen is intended for use by audiologists, ENTs and other health care professionals.

| Prescription Use X (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K122067